

MEDICINES CONTROL COUNCIL



MEDICINE SAFETY ALERT: NEW RESTRICTIONS ON THE USE OF GAMMA BENZENE HEXACHLORIDE (LINDANE) - CONTAINING SHAMPOOS

The Medicines Control Council (MCC) wishes to alert healthcare professionals and consumers to the risk of adverse events associated with the prolonged or repeated use of gamma benzene hexachloride (lindane)-containing shampoos (Gambex® and Quellada® Shampoos).

After a review of the risk-benefit profile of these products, the MCC, in consultation with the manufacturers of these products, has restricted the use of these shampoos. The MCC has also developed clear instructions and warnings for healthcare professionals and patients on their correct use.

The MCC recently received a case report of aplastic anaemia following the prolonged use of gamma benzene hexachloride containing shampoo despite a warning in the package insert. This triggered an urgent safety review of these products. It was of concern to the MCC that the product in this case was used repeatedly and for a prolonged period (three to four times per week for approximately six months).

Gamma benzene hexachloride is also known to be neurotoxic. Seizures are a well-described consequence of gamma benzene hexachloride particularly after repeated or prolonged application, but also in rare cases following a single application used according to directions.^{1,2,3}

After review the following decisions were taken by the MCC:

- Gamma benzene hexachloride is no longer indicated for the treatment of scabies.
- The indications for the use of gamma benzene hexachloride containing shampoo have been limited to the treatment of infestations with head lice (*Pediculosis capitis*), pubic lice (*Pediculosis pubis*) and crab lice (*Phthirus pubis*) in patients who are intolerant of, or who have failed to respond to other therapies.
- The sale of gamma benzene hexachloride products will be rescheduled to Schedule 2 (from Schedule 1) and the maximum pack size limited to 60 ml. Companies will be given a phase-out period of 12 months to introduce the new pack size but will be encouraged to speed up this process as much as possible and will be asked to incorporate the new warnings within 90 days of the date of the resolution.
- A Patient Information Leaflet (PIL) providing detailed instructions on the correct use of the product will be included in the packaging of these products.
- The outer container label will carry a boxed warning stating that "Excessive use leads to toxicity".

The manufacturers of gamma benzene hexachloride containing products are in the process of complying with these resolutions, including updating the labelling, package inserts and patient information leaflets to include clear and comprehensive instructions on the use of the products, and on warnings, side effects and special precautions.

Healthcare professionals are advised to:

- Carefully review the amended package insert and patient information leaflet before using or recommending the use of gamma benzene hexachloride containing shampoos.
- Inform patients and their caregivers of the correct use of these products and the importance of adhering to the recommendations in terms of the potential risks of inappropriate use of the product. Patients and/or their caregivers should be provided with a PIL.
- Advise patients and caregivers to seek medical care if they are unresponsive or intolerant of therapy with these products.
- Health Care Professionals are encouraged to report any adverse reactions associated with the use of medicines to the MCC's National Adverse Drug Event Monitoring Centre (NADEMC) by telephone (021 447 1618), by fax (021 448 6181) or by mail to Department of Health, Registrar of Medicines, Private Bag X828, Pretoria, 0001 or the manufacturer.

References:

1. Important safety information. Lindane facts: The truth about lindane. <http://www.lindane.com/lindane-safety-information/> (accessed on 4 April 2009).
2. Solomon BA, Haut SR, Carr EM, Shalita AR. Neurotoxic reaction to lindane in an HIV-seropositive patient. An old medication's new problem. J Fam Pract. 1995 Mar; 40(3):291-6.
3. FDA Public Health Advisory: Safety of Topical Lindane Products for the Treatment of Scabies and Lice. <http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm>